Sustainable vaccine policies in the EU

VACCINATION PROGRAMMES

1. INTRODUCTION

Vaccination programmes in many countries are facing new challenges, such as a decline in vaccination coverage or how to introduce new vaccines with limited resources.

The purpose of this first section is to provide the basis for a discussion on where and how strengthened EU-wide collaboration would create benefits for the modernization and implementation of vaccination programmes. Against the background of limited national resources and declining public trust in vaccination, the paper identifies synergies of potential EU actions that could strengthen transparency, evidence-base and financial sustainability of vaccination programmes.

2. CHALLENGES

The success of routine immunization depends on a comprehensive national vaccination programme and its implementation. But routine immunization often lacks resources, transparency and clarity. There is a need for evidence-based decision-making, data on the impact of vaccination programmes and financial sustainability in the context of reduced public health budgets.

2.1 Evidence-based policy-making of national vaccination programmes

2.1.1 Vaccine schedules

In the EU, vaccination programmes are within the competence of the Member States. Consequently, there are differences in the way programmes are planned, organised, and conducted.

The diversity of vaccination schedules are the result of national traditions and historical vaccine registrations in the Member States. They are often designed following the agenda of the overall prevention programme and as regards e.g. diphtheria, tetanus are based on studies that were conducted in the 1950s and 1960s.[1]

New scientific studies would be needed to improve the effectiveness of vaccination programmes as regards demographic and epidemiological changes in Europe. This includes the complex interactions between vaccination, waning immunity and the need for strong observational data for an ageing population.[2]

Furthermore, there would be need to develop a framework that clarifies and standardizes definitions of key elements of a vaccine schedule, relevant health outcomes and populations that are potentially susceptible to adverse effects.[3] Against this background, and in the face of challenges related to limited resources, vaccine scepticism and vaccine shortages, some Member States have indicated interest in reflecting on possible cooperation as regards the development of national vaccine schedules.

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[1] https://www.rki.de/DE/Content/Service/Publikationen/Downloads/1095.pdf?__blob=publicationFile
[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2677258/
[3] https://www.nap.edu/read/13563/chapter/2

To this end, the European Centre for Disease Prevention and Control (ECDC) is working with national vaccination advisory groups to strengthen efficiency in their decision-making making process, to optimize use of resources and avoid duplication of work. However, these activities should also take into account health assessment technology (HTA) as this would allow addressing systemic challenges faced by health care systems, assessing the effectiveness and efficiency of vaccines in the context of the whole health system and informing the prioritisation of health care services.

2.1.2 Vaccine impact and effectiveness studies

There would be added value to develop studies on vaccine effectiveness and vaccination impact at EU level to align methodology and facilitate the generation of a wide set of surveillance data across countries. In addition this would support countries with limited capacities and resources to conduct comprehensive post-licensing studies to assess the impact of vaccination programmes. These studies require sustainable funding and the development of appropriate platforms to facilitate the generation of data within and across countries.

2.1.3 Generation and use of quality vaccination data

Access to complete immunisation records helps to ensure that individuals receive the recommended vaccines. High quality data and its effective quality assessment are required to accurately measure and evaluate the impact of public health interventions and outcomes. However, many Member States have found it difficult to establish electronic immunization information systems that consolidate vaccination records, due to strict data protection laws.[4] These systems can also be used to increase and sustain high vaccination coverage through identification of pockets of unvaccinated individuals or groups and serve as a basis for tailored vaccination campaigns.

2.2 Financial sustainability

Financing of vaccination is an integral part of overall health sector financing, planning, and budgeting.[5] Spending on prevention and public health is the hardest-hit by budgetary cuts, while being on average already low at 2.7 % of health care systems budgets. Similarly, the vaccination programme accounts for a smaller fraction of the health system budget in comparison to other preventive and curative programmes[6], although mass secondary preventive therapies are probably at least three times more costly than life course vaccination.[7]

Vaccination programmes in a number of countries face challenges regarding reliability of funding and predictability of resources. Funding is needed to ensure sustainability of routine immunization, conduct of catch up campaigns for supplementary immunization activities, introduction of new vaccines, stockpiling, and multi-annual financial planning.

[4] http://www.eurosurveillance.org/images/dynamic/ee/v17n16/art20151.pdf
[5] http://siteresources.worldbank.org/HEALTHNUTRITIONANDPOPULATION/Resources/281627-1292531888900/IMMUNIZATIONFINANCINGTOOLKITFINAL121410.pdf
[6] http://www.sciencedirect.com/science/article/pii/S0264410X0801400X
[7] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4994732/

3. OPPORTUNITIES

3.1 Evidence-based policy making of national vaccination programmes

3.1.1 Vaccine schedules

There are strong arguments for moving towards more aligned vaccine schedules among Member States. In the context of free movement of people within the EU more aligned vaccine schedules would allow reducing the number of doses and vaccine combinations administered in different Member States. This would also facilitate the work of health care personnel that could vaccinate foreign children just according to the age, without following complex algorithms and recommendations.

Furthermore, such an approach would facilitate the central authorisation of vaccines as it would lower the number of local safety and immunogenicity studies and decrease the number of unnecessary blood tests in small children. In addition, aligned vaccine schedules would mitigate the need to justify or at least explain the general public the reason why the same vaccine product is utilized in different ways (dosage and timing) in different countries where the epidemiological situation is fairly similar. This would maintain and increase trust and confidence in vaccination programmes and vaccines. Moreover, this would help improving programme monitoring as it would facilitate comparing national programmes and benchmarking at the European level.

Collaboration of national vaccination advisory bodies at EU level would allow addressing a number of these issues. In addition, this would increase visibility and transparency of their work and allow clarifying the role of national advisory groups in the national vaccination decision-making process. Linking such work with the EU Health Technology Assessment Network would enable to make use of an established structural framework of cooperation at EU level, taking into account that vaccination is a core element of primary health care. To this end, this would also be a chance to strengthen Europe´s position in the global vaccine area.

3.1.2 EU vaccine impact and effectiveness studies

Against the background of current challenges related to vaccine effectiveness surveillance the establishment of EU-wide vaccine effectiveness monitoring could rapidly deliver robust quantitative data for the assessment of the impact and effectiveness of vaccination programmes, taking into account the cross-border nature of vaccine-preventable diseases. This would optimize the use of limited national resources, enhance comparability of study results and help decision-makers to clarify the type of information needed to assess the impact of a vaccination programme. As regards vaccine safety monitoring, a large, common, monitoring system for adverse events would allow to respond quickly to signals.

3.1.3 Generation and use of quality vaccination data

A reform of the EU data protection rules in 2016 established a modern and harmonized data protection framework across the EU[8] to ensure that health information is available as a means to deliver health care

[8] http://ec.europa.eu/justice/data-protection/reform/index_en.htm

services, while striking the right balance with personal data protection. Immunization information systems are pivotal in ascertaining and improving individual and population-level compliance with vaccination schedules as they increase transparency for stakeholders, in particular patient´s and health care professionals. These systems could be used to identify at-risk populations for vaccine-preventable diseases or to document and increase vaccination coverage. Against this background, the feasibility of establishing, updating or linking immunization information systems/electronic immunization registries could be explored. This would allow the establishment of standards for national immunization registers; exploring the full surveillance and research potential of such systems; and leveraging EU-wide activities in the area of risk-benefit monitoring. Such opportunities could also be explored in the context of the completion of the Digital Single Market.

3.2 Financial sustainability

The Commission intends to develop technical guidance on the development and monitoring of financial vaccination sustainability plans in order to raise awareness of the potential of such instruments. This will include e.g. the identification of core elements required to inform advocacy strategies for policy makers with a view to investing in immunization and securing sustainable funding of vaccination programmes.

Furthermore, Member States could optimise their use of the different available EU funding instruments to finance infrastructure needs of vaccination programmes in the context of strengthening ICT applications for e-health[9] to strengthen the (cross-border) interoperability of immunization information systems and leverage cooperation in the area of vaccine benefit/risk monitoring.

[9] http://www.esifforhealth.eu/pdf/WP2_Guide_FINAL_20150211.pdf

VACCINE SHORTAGES

INTRODUCTION

A "vaccine shortage" characterises insufficient vaccine security and the related difficulties countries have to access vaccines. In September 2015 77% of countries of the European Region countries reported shortages.[10]

This section provides the basis for a discussion on where and how strengthened EU-wide collaboration could create benefits for addressing challenges related to vaccine shortages and strengthening vaccine supply in Europe.

1. CHALLENGES

2.1 Vaccine supply issues

Supply factors relate to the production capacity for vaccines as well as market conditions, and influence availability of vaccines. The limited number of vaccine suppliers and limited production capacities and closing of production sites lead to a tenuous balance between demand and supply in many individual vaccine markets. Moreover, EU based manufacturers contribute 80 % to global vaccine production and 86 % of the vaccines produced in the EU by "Vaccines Europe" members are exported worldwide.

2.2 Vaccine demand issues

Demand factors relate to lack of flexibility (access to alternative products in case of shortage) and lack of predictability of demand (accurately forecast demand and have appropriate measures in place).

2.2.1 Lack of demand predictability

Limited resources and growing vaccine hesitancy, often linked to a lack of confidence in vaccines contributes to poor demand predictability. This can translate into inadequate national financing as well as inefficient use of available resources, which may affect the maintenance of immunisation services.

2.2.2 Little demand flexibility

Insufficient demand flexibility is related to policy and decision making processes, regulatory barriers, storage management policy, procurement procedures, and limited evidence on product interchangeability. All this limits access to alternative products if one product is in short supply. As tenders are often awarded to only one manufacturer/product, countries rely on only one supplier for each vaccine, increasing the risk of shortages.

2.3 Information

Strategic planning for global supply is missing. Limited knowledge of decision-makers on current and potential manufacturing capacity and no information-sharing between industry and public health authorities as regards to plans for new vaccination policies and schedule recommendations can impact country demand patterns and may therefore disrupt the balance between supply and demand if not anticipated. This can lead

[10] http://www.vaccineseurope.eu/about-vaccines/vaccines-europe-in-figures/

to shortages because of the lead-time necessary for industry to scale up production. There are also shortcomings as regards information about manufacturing issues and market demand from industry to member states.

2. OPPORTUNITIES

3.1 Supply side actions

3.1.1 Vaccine producers

Vaccine producers have to comply with the legal obligations laid down in Directive 2001/83/EC[11] on the obligation of continuous supply. In order to anticipate possible problems and plan for solutions that could alleviate any foreseen shortages, e.g. flexibility around packaging and labelling companies should be proactive in liaising with regulators. Creative solutions allowing for a larger buffer in terms of production capacity would deserve further discussion. Timely communication is crucial.

3.2 Demand side actions

3.2.1 Flexible handling of vaccine calendars

The European Centre for Disease Prevention and Control (ECDC) has provided technical assistance to EU/EEA Member States proposing options for possible solutions, particularly in terms of prioritisation of target groups for vaccination and potential temporary adjustments to national vaccination programmes to address the shortage of cellular pertussis containing vaccines.

3.2.2 Management of vaccine procurements

Member States or their designated private or public institutions that procure their vaccines directly from suppliers have complete autonomy over the vaccine selection, pricing, and delivery process. To leverage and strengthen vaccine procurement Member States can collaborate with other EU countries to build a regional procurement process. Furthermore, Member States may use on a voluntary basis a joint procurement mechanism according to Decision 1082/2013 on serious cross-border health threats, which is currently being discussed for a number of vaccines.

3.2.3 Vaccine supply and demand forecasting

Vaccine supply and demand forecasting is of central importance to ensure vaccine security.[12] Without the ability to forecast demand with reasonable certainty and some assurance of a viable market, manufacturers cannot scale production capacity, make commitments to suppliers of raw materials or justify a business case for investing in costly clinical trials to develop products.

National governments rely on demand forecasts for budgeting, while health programmes and implementing agencies depend on forecasts to plan their supply chain logistics.[13] Improved vaccine supply and demand forecasting would highlight key demand- and supply-side constraints, providing manufacturers with

[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF
[12] http://www.who.int/immunization/sage/meetings/2016/april/1_Mariat_shortages_SAGE_2016.pdf
[13] http://www.cgdev.org/files/13784_file_RiskyBusinessFull.pdf

information about new market potential, while allowing national governments to efficiently allocate resources by fostering appropriate prices and adequate supplies of products. [14] Ongoing activities could be taken into account as regards establishment of central databases/repositories of demand and supply data for medical products.[15]

The identification of principles on vaccine forecasting would allow to describing how to design and manage good forecasting processes. In this regard it would be crucial to ensure that the forecasting is independent and transparent. Furthermore, such principles could address the need to create a credible forecasting process and help develop and explain the forecast in relation to the overall market and the public policy environment. Work in this area could explore feasibility, requirements and possible key functions of a central repository of relevant demand and supply data, but also issues related to qualifications of a host institution and implementation of such an activity.

3.3 Information side actions

Dialogue between public health authorities and industry

Constructive dialogue between all stakeholders involved need to be intensified in order to increase mutual understanding and balance vaccine demand and vaccine supply in a pro-active and sustainable way.

Appropriate dialogue between industry and public health authorities could focus on manufacturers´ responsibility to ensure the availability of vaccines, the existence of manufacturing facilities in the EU, and the need for research on vaccine manufacturing process technologies to accelerate scalability of production and improve robustness of the vaccine manufacturing process.

[14] http://www.cgdev.org/files/13784_file_RiskyBusinessFull.pdf
[15] http://www.cgdev.org/doc/ghprn/DF_Exec_Summary.pdf

DISCUSSION

- What actions are necessary to strengthen vaccine surveillance monitoring and to increase the visibility of the impact of vaccination programmes?

- In which areas would it be important to continue/strengthen and support new EU actions to address challenges linked to sustainability of vaccination programmes?

- Which tools and mechanisms have proven effective to support better planning of vaccines supply and demand at a global level? Should this experience be transposed in the EU?

- What are the needs of vaccine manufacturers and how could a better dialogue help to achieve better vaccination results, and better delivery and forecasting?

- How can we establish a constructive dialogue between public authorities, industry and civil society to address and mitigate shortages in vaccines?